

Showdown Set Tuesday on Heart-Drug Study

By Morton Mintz

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Even a couple of years ago it would have been a sure thing. Philanthropist Mary Lasker's "citizen witnesses"—usually scientists from the medical research establishment—would go to Capitol Hill to testify that the cause was good and the need great. The chairmen of the health appropriations subcommittees, pre-sold admirers and believ-

ers both, would agree. And the money would be routinely appropriated, because in these matters, what Rep. John E. Fogarty (D-R.I.) and Sen. Lister Hill (D-Ala.) wanted, they got.

Only traces of the benign certainty of the old days will be evident tomorrow when, tentatively, House and Senate conferees will meet to approve, dilute or reject one of the last great efforts of the Lasker forces—a proposed \$5-

million item for massive tests of Atromid-S, a patented prescription drug, to see if it is useful in preventing heart disease.

Sen. Hill will be leading the fight for the appropriation, a "starter" on a study that ultimately would cost an estimated \$50 million. The battle will be one of his last, because he is retiring from the Senate at year's end.

But John Fogarty, his longtime ally, is dead. Now, in the House subcommittee he headed, skeptical voices are heard, especially that of Rep. Neal Smith (D-Iowa). And, in a new development Saturday, Smith released a letter opposing the Atromid-S project from Dr. James A. Shannon, who until a few days ago was director of the prestigious National Institutes of Health.

Replying on Aug. 5 to questions from Smith, Dr. Shannon said that he and the National Heart Institute consider a separate Atromid-S study "not . . . high priority."

He said that Atromid-S already is among four cholesterol-lowering drugs being studied in the Heart Institute's Coronary Drug Project. When this study is completed in

1974, Dr. Shannon said, there will be "a definitive answer to the question of the critical effectiveness of these drugs" in reducing the incidence of heart attack and death in men who have had one or more attacks.

To date, none of the four drugs has shown any "significant superiority" over the others, Dr. Shannon said.

Smith asked if the taxpayers should finance a study for Atromid-S alone which, by Shannon's estimate, would require 20,000 persons—2½ times as many as will be in the Coronary Drug Project when enrollment is completed by next July. These would be women as well as men who—unlike the men in the drug project—never have had a heart attack.

"It would be prudent to await the results (of the Coronary Drug Project) before committing thousands of normal subjects to any drug treatment regimen in the hope of preventing coronary heart disease without better knowledge of the attendant risks," he said.

Dr. Shannon told Smith that "there has been a group of

side effects and possible toxic effects (with Atromid-S) which warrants continued close monitoring of this drug before it can be recommended for unqualified long-term usage."

The views of Dr. Shannon and the Heart Institute were not sought by Hill. Instead, the Senator took testimony only from advocates of an Atromid-S study.

One was Dr. Louis R. Krasno, clinical research director in San Francisco for United Airlines.

Since April, 1965, he has tried Atromid-S in 700 men, comparing them with 700 untreated controls (last October, another 1000 men were added). These limited trials were single-blind, that is, the investigators—but not the patients—knew whether the participants were receiving a drug or a dummy pill. Single-blind tests do not eliminate the possibility of bias, as do double-blind trials in which neither patient nor physician knows if the pill is drug or placebo. The Coronary Drug Project is double-blind.

Last July, Sen. Hill said that the Krasno tests showed "an enormous drop in the death rate . . ." Dr. Shannon, how-

ever, told Rep. Smith that the results, which he called "encouraging," "cannot be considered evidence of effectiveness in preventing coronary heart disease."

Last spring, a publicity blitz based on the Krasno study was mounted by the Lasker forces. The theme was that Atromid-S may prevent heart attacks. In June, however, the theme was repudiated by the manufacturer, Ayerst Laboratories.

In a "corrective letter" sent at the insistence of the Food and Drug Administration, Ayerst apologized to the medical profession for an advertisement implying that Atromid-S is beneficial in heart disease.

The firm also acknowledged to doctors that the ad failed to call attention "to a number of the more serious side effects . . ." A year earlier, John M. Weiner of the University of Southern California testified before Hill that Atromid-S was "free of serious side effects."

After failing last year, the "starter" appropriation was revived this spring. Although it was spurned in the House, the Senate approved it after Hill, in an unusual example of legislative geographics, assigned it—in the Department of Health, Education, and Welfare money bill—not to the Heart Institute, but to "Regional Medical Programs."

His Senate Appropriations Committee report said, "If large-scale studies were done the results of the limited (Krasno) tests might well be substantiated. If so, the drug in general use would save hundreds of thousands of people from heart attacks and death every year."